



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT OPERATION

In re Application of:

Kositprapa et al.

Serial No.: 10/664,803

Group Art Unit: 1614

Filed: September 19, 2003

Examiner: N/A

For: NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE AND A THIAZOLIDINEDIONE DERIVATIVE

New York, NY 10036 February 28, 2006

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying

Form PTO/SB/08A.

Document

Designation

Relevance

BO

U.S. 6,099,862

Relates to oral dosage form for the controlled release of a

biguanide and sulfonylurea.

BP

U.S. 2003/0077297

Relates to pharmaceutical formulations and systems for improved

absorption and multistage release of active ingredients.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

on February 28, 2006-

John F. Volpe, Reg. No.57,383

Document <u>Designation</u>	Relevance
BQ U.S. 2003/0224046	Relates to unit dose combination composition for the simultaneous delivery of a short-acting and long-acting oral hypoglycemic agent.
CU WO 99/47125	Relates to method of treating a bacterial infection comprising amoxicillin and potassium clavulanate.
CV EP 1 588 708 A1	Relates to process for producing coated preparation and specifically to applying an immediate release layer of pioglitazone to a metformin core. See Examples 7 and 10 and Experimental Examples 1 and 2.

DN Relates to metformin dosage formulation.

Abdallah et al. Preparation and Evaluation of Metformin Hydrochloride Controlled-Release Tablets STP Pharma 4(1) pp. 15-20, 1988.

In accordance with current Patent and Trademark Office practice, no copy of the above listed United States Patents or applications are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a

fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,

John F. Volpe Reg. No. 57,383

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PTO/SB/08A (08-03)

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Sheet 1

## TRADEN! INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Complete if Known		
Application Number	10/664,803	
Filing Date	September 19, 2003	
First Named Inventor	Unchalee Kositprapa	
Art Unit	1614	
Examiner Name	Not yet assigned	
Attorney Docket Number	141-424	

		·		T DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
	BO	US- C 000 000	00 00 2000	Chan et al	
	во	<sup>US-</sup> 6,099,862	08-08-2000	Chen et al.	
	BP	<sup>US-</sup> 2003/0077297	04-24-2003	Chen et al.	
	BQ	US- 2003/0224046	12-04-2003	Rao et al.	
		US-			
	<u> </u>	US-			
		US-			

	FORE	IGN PATENT DOCL	JMENTS	•	
Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
 CU	WO 99/47125	04-12-2005	Conley et al.		
CV	EP 1 588 708 A1	10-26-2005	Tekeda Pharm. C		
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Examiner	Date
Signature	Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO	Complete if Known		
Capatitate for form 1443/110	Application Number	10/664,803	
INFORMATION DISCLOSURE	Filing Date	September 19, 2003	
STATEMENT BY APPLICANT	First Named Inventor	Unchalee Kositprapa	
(Use as many sheets as necessary)	Art Unit	1614	
(ose as many sneets as necessary)	Examiner Name	Not yet assigned	
Sheet 2 of 2	Attorney Docket Number	141-424	

	NON PATENT LITERATURE DOCUMENTS	
Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
DN	ABDALLA ET AL, Preparation and evaluation of Metaformin Hydrochloride Controlled-Release Tablets, STP Pharma 4(1) pp. 15-20, 1988.	
	No. <sup>1</sup>	No.1 the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  ABDALLA ET AL, Preparation and evaluation of Metaformin Hydrochloride

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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1 Applicant's unique citation designation number (optional). 

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